IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION; NORTH AMERICAN CUSTOM LABORATORIES, LLC D/B/A FARMAKEIO CUSTOM COMPOUNDING, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; and DR. ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, 10903 New Hampshire Ave., Silver Spring, Maryland 20903 Defendants.	Civil Action No. 4:24-cv-953

COMPLAINT

Plaintiffs Outsourcing Facilities Association ("OFA") and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), by and through undersigned counsel, allege as follows:

Nature of the Action

1. At issue in this case is a reckless and arbitrary decision—lacking any semblance of lawful process—by the Food and Drug Administration ("FDA") to deprive patients of a vital treatment for type 2 diabetes and obesity, two of the most common and harmful medical conditions in existence. Tirzepatide, an active ingredient that treats those conditions, has been provided to patients in large part through lawful drug compounding under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Compounding is the process by which a doctor, pharmacist, or licensed

outsourcing facility combines, mixes, or alters ingredients to create medicines tailored to patient needs. Congress determined that, when a drug is in short supply, compounding is an efficient, effective, and appropriate means to ensure that patient treatment can occur, notwithstanding the shortage. FDA placed Tirzepatide on the shortage list in December 2022, and since then, patient demand has been satisfied in precisely the manner Congress contemplated: pharmacies and outsourcing facilities—including Plaintiffs and their members—have compounded Tirzepatide to meet a large segment of market demand.

2. But on October 2, 2024, FDA changed all that with a post to its website, abruptly depriving patients of much needed treatment and artificially raising drug prices. Ignoring evidence that the shortage persists, FDA removed Tirzepatide from the shortage list without notice, without soliciting input from affected parties and the public, and without meaningful rationale. Indeed, the agency *confirmed* that there remains a Tirzepatide shortage and that it acted to benefit special interests, raise drug prices, and deprive much of the public of access to a needed medicine. The only basis FDA offered for its declaration of victory over the shortage was the "stated product availability and manufacturing capacity" of the drug's manufacturer—the company that is self-interested in monopolizing the market. The sole factual assertion FDA made concerning a shortage was that it *persists*: "Patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies." Put simply, FDA knows its action will leave many patients with no effective treatment but persisted with that action anyway on an expedited basis and without warning.

3. If ever an agency action were arbitrary, capricious, and contrary to law, this is it. The Administrative Procedure Act (APA) secures the foundational principle that "the Government should turn square corners in dealing with the people," just as regulated parties "must turn square

corners when they deal with the Government." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 24 (2020) (citations omitted). Under the APA, FDA's decision to remove a drug from the shortage list is clearly a "substantive" rule, which means a rule that establishes legal rights and duties. Because of the profound impact of substantive rules, the APA demands that agencies undergo notice-and-comment rulemaking before promulgating them: an agency must propose and give notice of its action in the Federal Register, solicit comments from interested parties, and in its final decision explain its rationale and address the meaningful comments it receives in a reasoned and transparent decision. Agencies across the massive federal bureaucracy do these things every day of the week. But FDA skipped past every single requirement of reasoned rulemaking when it threw up a notice on its website removing Tirzepatide from the shortage list—thereby depriving patients of access to the compounded drug. This Court's immediate intervention is essential to protect the many patients who rely on compounded Tirzepatide and vindicate Congress's insistence on reasoned, informed rulemaking by federal agencies.

Parties

4. Plaintiff Outsourcing Facilities Association ("OFA") is a trade association representing outsourcing facilities that engage in drug compounding under federal law, including facilities that compounded Tirzepatide until October 2, 2024. As explained below, all OFA's members are prohibited from compounding Tirzepatide by the final agency action challenged in this case. OFA's mission is to represent and advocate for the interests of outsourcing facilities and to educate the public and policymakers about the essential services and products provided by outsourcing facilities.

5. Plaintiff North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding ("FarmaKeio"), is a Texas limited liability company headquartered in

Southlake, Texas. FarmaKeio has been compounding Tirzepatide in compliance with federal law, and its compounding activities are directly regulated by FDA. FDA's final agency action in this case restricts Tirzepatide compounding by FarmaKeio, as explained below.

6. Defendant FDA is a federal agency of the United States Government headquartered in Silver Spring, Maryland. It is an agency for purposes of the APA and is subject to its requirements.

7. Defendant Dr. Robert M. Califf is the Commissioner of Food and Drugs and is named in his official capacity only.

Jurisdiction and Venue

8. This Court has jurisdiction over Plaintiffs' APA causes of action under 28 U.S.C. § 1331. Through the APA, the United States has waived sovereign immunity from this lawsuit. *See* 5 U.S.C. § 702.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because Plaintiff FarmaKeio resides in this district, as do certain members of Plaintiff OFA, and a substantial part of the events or omissions giving rise to the claim occurred in this district, where FDA's final action is directly regulating Plaintiff FarmaKeio and OFA members and prohibiting activity that was lawful until October 2, 2024.

Factual and Legal Background

Congress Identifies Compounding as an Effective, Efficient, and Appropriate Means of Meeting Patient Need and Market Demand During Drug Shortages

10. "Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," typically one that is "not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Compounding "is a traditional component of

the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Id.* at 361 (internal citation omitted). "Many States specifically regulate compounding practices as part of their regulation of pharmacies," and "[s]ome require all licensed pharmacies to offer compounding services." *Id.*

11. Congress regulated drug compounding in two provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), Section 503A, 21 U.S.C. § 353a, and Section 503B, 21 U.S.C. § 353b.

12. Section 503A regulates pharmacy compounding. Compounding that meets the requirements of this section is exempted from the FDCA's new-drug approval requirement, as well as certain drug-adulteration and branding standards. 21 U.S.C. § 353a(a). To qualify for Section 503A treatment, a drug must, *inter alia*, be compounded "on the prescription order for [an] individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs" or, if it occurs "before the receipt of a valid prescription order for such individual patient," it must be "based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product." *Id.* § 353a(a)(2)(A) and (B).

13. Section 503A authorizes compounding from "bulk drug substances," which are active ingredients typically of FDA-approved drugs, so long as the pharmacy "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." *Id.* § 353a(b)(1)(D).

14. Section 503B establishes a separate regime governing "outsourcing facilities" that may compound drug products not based on existing prescriptions or a history of prescriptions if numerous requirements are satisfied. *Id.* § 353b. Section 503B subjects outsourcing facilities to registration, inspection, and reporting requirements and other regulations, *see id.* § 353b(a)(1) and

(b), and exempts from the new-drug approval process and other FDCA requirements "a drug compounded…in a facility that elects to register as an outsourcing facility if each of" 11 conditions are met, *id.* § 353b(a).

15. Central to the compounding regulations of Sections 503A and 503B is the drug shortage list required by Section 506E. That section requires FDA to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." 21 U.S.C. § 356e(a). The provision requires that FDA identify for "each drug on such list" "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the Secretary." *Id.* § 356e(b)(1)–(4). The FDCA defines the term "drug shortage" to mean "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2).

16. Section 506E does not identify procedures FDA must comply with in removing a drug from the shortage list and does not displace default provisions of the APA governing FDA action in removing drugs from the shortage list.

17. When a drug is on the shortage list, Section 503A pharmacies and Section 503B outsourcing facilities are permitted to engage in compounding from its active ingredients that is unlawful if the drug is not listed on the shortage list.

18. Under Section 503B, compounding from bulk drug substances (i.e., active ingredients) is impermissible unless "the drug compounded from such bulk drug substance appears on the drug shortage list…at the time of compounding, distribution, and dispensing" or, alternatively, the bulk drug substance appears on a separate list of ingredients for which there is a "clinical need." *Id.* § 353b(a)(2)(A)(ii). FDA has narrowly construed the "clinical need" path to

bulk-drug compounding, such that an FDA-approved drug not in shortage will virtually never meet the clinical-need standard. *See Athenex Inc. v. Azar*, 397 F. Supp. 3d 56 (D.D.C. 2019). As a result, FDA will typically consider bulk drug compounding from the active ingredients of an FDA-approved drug unlawful, unless the drug is listed on the shortage list.

19. A drug's listing on the shortage list carries a second, independent consequence under Section 503B. That section bars compounding of any kind of a drug that is "essentially a copy of one or more approved drugs." *Id.* § 353b(a)(5). But the statutory definition exempts from the definition of "essentially a copy of an approved drug" any drug that "appears on the drug shortage list…at the time of compounding, distribution, and dispensing." *Id.* § 353b(d)(2)(A). Consequently, if a drug appears on the shortage list, compounding of the drug will be permitted, even if it results in a drug that is essentially a copy of the FDA-approved drug. Otherwise, essential-copy compounding is unlawful, even if the active ingredient appears on the clinical-need list.

20. The effect of a drug-shortage listing is similar under Section 503A. As noted, compounding "in inordinate amounts" of "any drug products that are essentially copies of a commercially available drug product" does not qualify for protection under Section 503A. *Id.* § 353a(b)(1)(D). But FDA reads the term "commercially available drug product" not to include drugs listed on the shortage list, since such drugs are by definition not commercially available. *See* Food and Drug Administration, Compounding when Drugs are on FDA's Drug Shortages List, https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list. As a result, Section 503A pharmacies may compound essential copies of FDA-approved drugs that are on the shortage list.

21. FDA treats drug compounding that does not meet the standards of Section 503A or 503B as a violation of the FDCA. Violations are subject to penalties. *See* 21 U.S.C. § 331(d) (prohibited acts); 21 U.S.C. § 332(1) (injunctions); 21 U.S.C. § 333 (penalties); 21 U.S.C. § 335a (debarment). Accordingly, listing of a drug on the shortage list marks the difference between a lawful business enterprise and a federal-law violation.

22. This scheme reflects a decidedly patient-focused orientation of compounding restrictions under the FDCA and, specifically, Congress's considered judgment that compounding by pharmacies and outsourcing facilities is an efficient and effective means of ensuring patient needs are satisfied when an FDA-approved drug is in shortage.

FDA Abruptly Declares Victory Over a Drug Shortage That Manifestly Persists Without Notice, Opportunity to Comment, or a Reasoned Decision

23. Tirzepatide is the active ingredient an FDA-approved prescription drug used for the treatment of type 2 diabetes and for obesity, which is recognized in the medical field as a chronic disease that results in substantial global morbidity and mortality. Tirzepatide is administered via subcutaneous (i.e., under-the-skin) injections and is sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss.

24. Tirzepatide has been proven effective in treating weight loss in particular, and, given the prevalence of this condition nationwide, the drug is in exceptionally high demand.

25. On or about December 15, 2022, FDA listed Tirzepatide injection on the Section 506E shortage list, noting 10 forms of Mounjaro and Zepbound injections that are in shortage.

26. The drug listing enabled pharmacies and outsourcing facilities to satisfy demand and patient needs through drug compounding, including compounding of drugs that are essentially copies of FDA-approved versions of Tirzepatide.

27. Numerous pharmacies and outsourcing facilities, including the compounder Plaintiffs, compounded Tirzepatide under Sections 503A and 503B. From that point until October 2, 2024, a large portion of market demand and patient need nationwide was satisfied by compounded forms of Tirzepatide lawfully produced as Congress envisioned.

28. In fact, notwithstanding this effort, even after the FDA listing, demand for Tirzepatide continued to go unsatisfied or saw delays in satisfaction. Patient needs have in this entire timeframe gone unmet due to an ongoing shortage.

29. Various industry participants communicated with FDA, providing updates with evidence of extremely high demand for Tirzepatide, scarcity in various regions and at the national level, and delays in filling prescriptions. For the entire period during which FDA announced a shortage of Tirzepatide, the agency was in actual or constructive receipt of information demonstrating that supply continued to lag behind demand, even at stark levels. On information and belief, additional information was available to FDA demonstrating that supply continued to lag behind demand but was not considered because FDA failed to engage in a meaningful inquiry.

30. Despite the ongoing shortage, FDA abruptly announced on October 2, 2024, that "the shortage of tirzepatide injection, a glucagon-like peptide 1 (GLP-1) medication, has been resolved."

31. FDA first made this announcement around close of business Eastern Time, as the Jewish holiday Rosh Hashanah began, through a posting on its website.

32. FDA provided no notice of this announcement before it took legal effect (i.e., before the effectuation of delisting occurred). Market participants did not know before that moment that compounding activities they were currently undertaking in reliance on the listing would immediately become unlawful.

33. FDA provided no opportunity for public comment on whether to delist Tirzepatide.

34. By foregoing the public notice-and-comment process, FDA deprived regulated parties and other interested persons of the opportunity to comment on the proposed delisting of Tirzepatide and to provide probative information concerning the drug's availability. At the same time, FDA deprived itself of valuable information that would have been made available to it had the agency solicited public comment.

35. In addition, FDA's failure to follow the APA's procedures deprived all interested persons of a reasonable explanation for its decision. Among other things, FDA never addressed the voluminous evidence that demand for Tirzepatide exceeds supply and that compounding authorized by Sections 503A and 503B remains necessary for patient needs to be met and for market demand to be satisfied.

36. In its public notice, FDA supported its decision on the merits with only a single statement: "FDA confirmed with the drug's manufacturer that their stated product availability and manufacturing capacity can meet the present and projected national demand." Ex. A at 1. From this statement, it is clear that FDA's sole consideration in deciding the shortage had ended was information provided by the manufacturer of Tirzepatide.

37. While the FDCA requires FDA to consider information provided by a drug's manufacturer in addressing a shortage, it does not *limit* FDA to that information. To the contrary, an agency required by law to engage in informed decision-making must consider *all* relevant information at its disposal, not only information supplied by a self-interested market participant whose production failings caused the shortage in the first instance and which has an overriding incentive to make a one-sided presentation to the agency.

38. Further down in its notice, FDA offered a generic assertion that it typically "considers a variety of factors, including the company's ability to meet current and historical demand, the amount in a manufacturer's stock, affected market share, ability of alternate manufacturers to cover the demand, and confirmed market stabilization." Ex A at 2. But the notice says nothing of FDA's findings (even at a high level) under any of those criteria (or any others) concerning Tirzepatide. As noted, the sole case-specific assertion in the notice references FDA's singular reliance on communications with Tirzepatide's manufacturer. This notice leaves the public in the dark as to why FDA disregarded the overriding evidence of continued gap between demand and that manufacturer's supply or whether FDA even considered such evidence at all.

39. In fact, in the very next sentence, FDA refuted its own finding that the drug shortage ended with the contrary warning: "Patients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies." Ex. A at 1.

40. For each of the 10 Tirzepatide injections on the shortage list (and now removed), FDA made the following finding (or a substantial equivalent):

> Even When A Medication Is Available, Patients May Not Always Be Able To Immediately Fill Their Prescription At A Particular Pharmacy. That Is Especially True For Refrigerated Products And Products With Multiple Dose Strengths, Due To Factors Like Ordering Practices And Incentives, Cold Chain Logistical Considerations, And Retailer Capacity Constraints. Patients May Experience Variability At A Particular Pharmacy Location Regardless Of Whether A Drug Is In Shortage.

Ex. B.

41. FDA's express recognition that "supply disruptions" will continue to thwart patient needs and leave market demand unsatisfied, and that patients may not always be able to immediately fill their prescription, is a confirmation on the face of FDA's notice that its

determination was arbitrary, capricious, and unsupported by anything but the self-interested assertions of a market participant. FDA's finding that "Factors Like Ordering Practices And Incentives, Cold Chain Logistical Considerations, And Retailer Capacity Constraints" continue to prevent supply from meeting demand confirms there is remains a shortage: those are the very factors FDA claims to consider in deciding whether a shortage exists, so its findings that those factors are preventing patient needs from being met is a finding that the shortage is ongoing.

42. FDA's notice also reflects no consideration of the large segments of the market for Tirzepatide that are served by compounded versions of the drug. FDA's notice does not provide any reason for it to conclude that supply will match or exceed demand after compounded forms of the drug are taken off the market.

43. FDA's decision came one day after port workers across the eastern seaboard and beyond—from Maine to Texas—commenced a labor strike that was projected to threaten imports and raise prices of goods across economic sectors. An FDA representative involved in the decision to delist Tirzepatide acknowledged to an OFA representative knowledge of the strike and of press coverage stating that the strike threatened supply of critical drug components for manufacturers of weight-loss drugs, including Tirzepatide. FDA's notice, however, neither reflects consideration of the strike nor provides a basis for the agency to believe the strike would not impact supply. Although the strike has been resolved for the time being, FDA had no way to know the length of the strike when it made its decision, and even a short strike is predicted to create continued supply chain disruptions. Its failure to address this issue reflects lack of reasoned decision-making and recklessness as to the true state of supply and demand in the market for Tirzepatide.

44. FDA's notice contains no finding or even assertion establishing that patient needs and market demand for Tirzepatide will be fulfilled beginning October 2, 2024.

45. FDA's notice cites no evidence establishing that patient needs and market demand for Tirzepatide will be fulfilled beginning October 2, 2024.

46. The very limited fact-related assertions related to Tirzepatide all suggest there is no basis for FDA's action deeming the shortage at an end, other than FDA's black-box reliance on manufacturer representation.

Plaintiffs Are Immediately Stifled in Their Efforts to Ensure Patients Receive Important Treatments at Reasonable Prices

47. Plaintiff FarmaKeio is a compounding pharmacy in Southlake, Texas that operates under Section 503A.

48. FarmaKeio compounded Tirzepatide pursuant to Section 503A and in reliance on Tirzepatide's drug-shortage status. With Tirzepatide removed from the shortage list, FarmaKeio will be unable to continue accepting prescriptions for Tirzepatide and filling them with compounded Tirzepatide. FarmaKeio would continue accepting prescriptions and filling them with compounded Tirzepatide but for FDA's action.

49. Plaintiff OFA is a trade association representing outsourcing facilities registered under Section 503B, including in this judicial district. All members of OFA are outsourcing facilities that compound drugs within the Section 503B framework. Because FDA removed Tirzepatide from the shortage list, and because Tirzepatide is not on the clinical need list, bulk compounding of Tirzepatide is now categorically unavailable under Section 503B and thus is prohibited to all OFA's members.

50. The compounded drugs produced by FarmaKeio and OFA's members helped meet patient needs, fulfilled market demand, and kept prices down. By consequence of Plaintiffs' compounding, patients' obesity and diabetes conditions were treated, even as FDA acknowledged their needs could not be met by the manufacturer of Tirzepatide.

51. Compounding by an outsourcing facility under Section 503B is expensive. OFA's members spent significant sums in sunk costs to support compounding operations. It can cost hundreds of thousands of dollars and takes months of lead-in effort to begin compounding in compliance with Section 503B. Additionally, an outsourcing facility experiences opportunity cost from compounding operations, as manufacturing lines are devoted to compound a drug (here, Tirzepatide) that can no longer be put to that use after the drug is removed from the list. It takes additional investment and time before the same manufacturing lines can be converted to other uses.

52. FDA's delisting of Tirzepatide will (if it stands) cause OFA's members to fail to capitalize on their investment. It will destroy their revenues (and those of FarmaKeio) from the sale of compounded drugs that are in acute demand. Even if Plaintiffs prevail in this action, they will be unable to recoup lost revenues or profits from the federal government.

53. OFA's members and FarmaKeio intend to continue compounding Tirzepatide on a prospective basis to continue meeting patient needs and market demand and would do so but for FDA's arbitrary and unlawful removal of Tirzepatide from the shortage list.

54. OFA's members invested in technology, equipment, space, human resources, and other assets in order to facilitate compounding Tirzepatide. Without court intervention or further action by FDA, these investments will be wholly or partially impaired or adversely impacted.

55. The shortage of Tirzepatide continues. Without lawful compounding under Sections 503A and 503B, patient needs will not be fulfilled and market demand will not be satisfied. Conditions treated by Tirzepatide will go untreated, resulting in further disease and increased mortality rates.

FIRST CAUSE OF ACTION
(Agency Rulemaking Without Requisite Notice, Comment, and Explained Decision)

56. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

57. The APA establishes a notice-and-comment rulemaking requirement that applies to all agency rulemaking, with limited exceptions that do not apply here. 5 U.S.C. § 553.

58. Under the notice-and-comment process, an agency must issue a notice of proposed rulemaking in the Federal Register with specified information (e.g., legal authority for the rule, description of the rule), solicit public comments for a period not less than 30 days, and review those comments. An agency must also respond to meaningful comments in its final rulemaking.

59. FDA's decision to remove Tirzepatide from the shortage list is final agency action that qualifies as an agency rule. A "rule" is defined to include "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). "[T]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make." *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023). FDA's delisting easily meets this definition.

60. FDA's delisting decision is a "legislative" rule that is subject to the notice-and-comment requirement because it "has the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Listing and removal mark the difference between a lawful compounding business enterprise and one FDA considers unlawful and subject to severe penalties. Accordingly, a delisting decision is a rule "affecting individual rights and obligations." *Chrysler Corp. v. Brown,* 441 U.S. 281, 302 (1979).

61. FDA's delisting decision is not eligible for the exemption from notice-and-comment requirements applicable to "interpretative rules, general statements of policy, or rules of

agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). FDA's delisting is not interpreting a legal provision, making a generic policy statement, or governing the agency's internal process. Rather, a delisting decision declares previously lawful activity, regarded by Congress's as beneficial, to be unlawful.

62. No provision of the FDCA "expressly" exempts FDA from the APA's notice-and-comment requirement, as is necessary for an organic statute to eliminate such a requirement. 5 U.S.C. § 559.

63. FDA did not engage in notice-and-comment rulemaking before issuing its final decision removing Tirzepatide from the shortage list.

64. FDA's final decision removing Tirzepatide from the shortage list is therefore "contrary to law" and "without observance of procedure required by law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A), (D). FDA's unlawful action entitles Plaintiffs to the relief requested below.

SECOND CAUSE OF ACTION
(Lack of Reasoned Decisionmaking by Omission of Rationale Sufficient to Explain Final Agency Action)

65. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

66. The APA obligates agencies to engage in reasoned decisionmaking and directs that their actions be set aside if arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020). This includes requirements that agencies consider relevant factors and provide an explanation for their final actions. *Id.* at 16, 20–24. This standard obligates an agency to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Because the agency's

disclosed bases for a final action supply the sole grounds on which it may be upheld in litigation, a failure to provide sufficient grounds for the decision, standing alone, requires vacatur of the decision and remand. *Regents of the Univ. of California*, 591 U.S. at 16.

67. FDA's sole basis for final action removing Tirzepatide from the shortage list was its representation that it "confirmed with the drug's manufacturer that their stated product availability and manufacturing capacity can meet the present and projected national demand." Ex. A at 1. But, as FDA's own notice acknowledges, the determination cannot be grounded solely on representations of a manufacturer: it must include consideration of "a variety of factors" including (without limitation) "the company's ability to meet current and historical demand, the amount in a manufacturer's stock, affected market share, ability of alternate manufacturers to cover the demand, and confirmed market stabilization."

68. FDA's notice of decision—the sole basis on which its decision could be upheld—says nothing of the manufacturer's ability to meet current and historical demand (apart from the manufacturer's own representations), the manufacturer's stock, affected market share, ability of alternate manufacturers to cover the demand, and confirmed market stabilization. FDA's notice of decision also says nothing of other factors, like patient needs, evidence of market scarcity, and regional supply and demand.

69. FDA's notice of decision, further, does not address evidence FDA received from market participants evidencing continued inability of supply cannot keep pace with demand. FDA's notice of decision does not address other evidence of which FDA was aware (or would have been aware on a reasonable inquiry) evidencing continued inability of supply to keep pace with demand.

70. FDA's notice of decision does not address the fact that large segments of the market, and much existing patient need, for Tirzepatide were (before October 2) being served by

compounded versions of the drug or that the delisting of the drug will prohibit much or all of the compounding of Tirzepatide to occur. FDA's notice of decision provides no reason for it to conclude that manufacture supply alone (without compounding) can meet patient needs or market demand. FDA's notice of decision does not acknowledge this phenomenon at all.

71. FDA's notice of decision does not address the likely impact of the massive port-worker strike commenced the day before the decision, even though FDA was aware of evidence that the strike will impact the supply chain for Tirzepatide and thereby its supply to patients.

72. FDA's final decision removing Tirzepatide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

THIRD CAUSE OF ACTION
(Lack of Reasoned Decisionmaking by Facially Contradictory Findings That Refute or Undermine the Basis of Final Agency Action)

73. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

74. The APA obligates agencies to engage in reasoned decisionmaking and directs that their actions be set aside if arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020). This includes requirements that agencies consider relevant factors and provide an explanation for their final actions. *Id.* at 16, 20–24. Because the agency's disclosed bases for a final action supply the sole grounds on which it may be upheld in litigation, a failure to provide sufficient grounds for the decision, standing alone, requires vacatur of the decision and remand. *Id.* at 20–24.

75. A corollary of these principles demands that agency determinations be founded on findings that are not themselves arbitrary and capricious. This principle forbids agencies to predicate their actions on determinations that are facially incoherent or inconsistent.

76. FDA's determination that "the shortage of tirzepatide injection, a glucagon-like peptide 1 (GLP-1) medication, has been resolved" is founded on facially incoherent and inconsistent findings.

77. The face of FDA's determination admits that "[p]atients and prescribers may still see intermittent localized supply disruptions as the products move through the supply chain from the manufacturer and distributors to local pharmacies." This means that, at the time FDA acted, supply did not satisfy demand and the shortage persisted. FDA's contrary determination, based on the manufacturer's "stated product availability" conflicts with the finding that disruptions will continue at least in the near term.

78. Moreover, FDA's findings for each form of Tirzepatide injection hold that "Patients May Not Always Be Able To Immediately Fill Their Prescription At A Particular Pharmacy," because of "Factors Like Ordering Practices And Incentives, Cold Chain Logistical Considerations, And Retailer Capacity Constraints." Ex. B. These are factors that all point to a drug shortage and do not in any way prove a drug shortage has ended. Yet FDA's notice contains not one finding of fact (aside from manufacturer statements) supporting its finding that the shortage ended. Its declaration that the shortage is over is arbitrary and capricious on its face.

79. At a minimum, the notice is contradictory and insufficient to support the final action. The notice makes no attempt to square the finding that the shortage has ended with the statements that supply disruptions are expected to continue. This incompatibility renders the notice arbitrary and capricious on its face.

80. FDA's final decision removing Tirzepatide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

FOURTH CAUSE OF ACTION
(Arbitrary and Capricious Determination That Tirzepatide Shortage Ended)

81. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

82. The APA forbids arbitrary and capricious agency action.

83. FDA acted arbitrarily and capriciously in determining that the drug shortage has ended in the face of overriding evidence that supply of Tirzepatide—including supply made possible by compounding—cannot keep pace with demand.

84. Market participants presented FDA evidence that patient needs and market demand for Tirzepatide is not satisfied by current supply, including supply made possible by compounding. Additional evidence was available to FDA that patient needs and market demand for Tirzepatide is not satisfied by current supply, including supply made possible by compounding, had it engaged in appropriate investigation.

85. FDA, however, rushed out a decision declaring the shortage had ended based solely (or primarily) on statements by the manufacturer that it can meet demand, despite substantial probative evidence proving to the contrary.

86. FDA's final decision removing Tirzepatide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

FIFTH CAUSE OF ACTION
(Unlawful Interpretation and Application of Drug Shortage Statute)

87. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

88. Agency action must comply with the law Congress imposed on that agency. Agency obligations under a statute are resolved through court determination of "the best reading of the

statute" without deference to the agency. *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2266 (2024).

89. FDA's notice of decision rests on an erroneous reading of statutes. The FDCA requires FDA to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." 21 U.S.C. § 356e(a). This leaves FDA no discretion to remove a drug from the shortage list in circumstances where "demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2).

90. But FDA's own findings represent that the projected demand for Tirzepatide will exceed supply of the drug. FDA found that "supply disruptions" will persist "Due To Factors Like Ordering Practices And Incentives, Cold Chain Logistical Considerations, And Retailer Capacity Constraints." Ex. B. The statute leaves FDA no avenue to remove a drug from the list in the face of its own findings to this effect.

91. FDA's final decision removing Tirzepatide from the shortage list is therefore "contrary to law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

SIXTH CAUSE OF ACTION
(Unlawful Failure to Publish Decision in the Federal Register)

92. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

93. The public information section of the APA obligates agencies to "publish in the Federal Register… (D) substantive rules of general applicability adopted as authorized by law." 5 U.S.C. § 552(a)(1)(D). This "was adopted to provide, inter alia, that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so

as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974)

94. FDA's decision to remove Tirzepatide from the shortage list is a legislative rule: it affects the individual rights of numerous market participants in a generally applicable manner, as well as the interests of innumerable patients who need Tirzepatide for their treatment.

95. FDA did not publish its decision in the Federal Register.

96. FDA's final decision removing Tirzepatide from the shortage list is therefore "contrary to law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

Prayer for Relief

Plaintiffs respectfully asks that this Court enter judgment in their favor and that they be granted the following relief:

A. Declare that FDA's final action removing Tirzepatide from the drug shortage list is contrary to law under the APA, which subjects that action to notice-and-comment rulemaking procedures;

B. Declare that FDA's final action removing Tirzepatide from the drug shortage list is arbitrary and capricious in violation of the APA;

C. Vacate and/or set aside FDA's final action removing Tirzepatide from the drug shortage list on the grounds stated above;

D. Permanently and temporarily enjoin FDA from taking action against Plaintiffs for engaging in compounding of Tirzepatide that is lawful in circumstances where Tirzepatide is named on the drug-shortage list;

E. Issue a temporary restraining order lasting 14 days enjoining FDA from taking action against Plaintiffs for engaging in compounding of Tirzepatide that is lawful in circumstances where Tirzepatide is named on the drug-shortage list during the time period when this Court adjudicates Plaintiffs' forthcoming motion for a preliminary injunction.

F. Award Plaintiffs their fees and costs related to this action, including reasonable attorneys' fees; and

G. Grant such other and further relief as the Court deems appropriate.

Dated: October 7, 2024

/s/ Ty Doyle

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